



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>In re</i> Application of:	)	Confirmation No. 3724
J. Kevin DONAHUE	)	Group Art Unit: 1636
Serial No. 09/977,865	)	Examiner: K. Katcheves
Filed: October 15, 2001	)	
For: <b>Methods and Compositions for</b>	)	
<b>Nucleic Acid Delivery</b>	)	Atty. Docket No. 001107.00449

**DECLARATION UNDER RULE 132**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, J. Kevin Donahue, declare:

1. I am a named co-inventor of the application named above. I am an Associate Professor of Medicine at The Johns Hopkins University School of Medicine in Baltimore, Maryland in the Division of Cardiology.

2. Following the teachings of the subject application, we have successfully delivered nucleic acids to cells in a tissue by perfusion through vasculature of a tissue of interest in whole animals. A cGMP-specific phosphodiesterase-5 (PDE-5) inhibitor was administered as a part of the procedure.

3. We used intracoronary perfusion to deliver nucleic acids to ten pigs that had been given oral sildenafil, a PDE-5 inhibitor. Gene transfer and expression was detected in 45% of the cells of the atrioventricular (AV) node. Other organs were found to express the transferred gene in less than 1% of the cells. When a gene encoding the

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